10/20/97

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
NCIB FSC 10/2

60 8th Street, N.E.
Atlanta, Georgia 30309

468

September 29, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

William Lamberson
Owner/President
Lamberson's Home Care, Inc.
3400 McClure Bridge Road, #D
Duluth, Georgia 30136

WARNING LETTER

Dear Mr. Lamberson:

An inspection of your medical oxygen transfilling facility was conducted on September 9 & 10, 1997, by Investigator Leah M. Andrews. Our investigator documented several significant deviations from the Current Good Manufacturing Practice Regulations (GMPs) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 211. These deviations cause your transfilled drug product, Oxygen USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

You have failed to assure that all compressed medical oxygen transfilled and distributed by your facility conforms to appropriate final specifications, to include purity, prior to release. A review of the batch production/transfilling records revealed [redacted] transfilled cylinders of released medical oxygen which did not have the purity that they purported to have and is required for such medical use. Oxygen USP must contain no less than 99.0% of Oxygen. The purity assay results were noted to range from 97.9% to 98.7% for all [redacted] purity tests performed over a span of [redacted] production days. This span included all purity tests performed since [redacted] 1997. The most commonly reported purity assay was 98.5% which was reported to the investigator as the [redacted] There was no indication that anyone in a responsible position at your firm understood the significance of these deficient assay results.

You have failed to maintain the appropriate documentation to verify that the oxygen analyzer was properly calibrated each day of use. There were no records of calibration for the analyzer available at your firm since December 17, 1996. Oxygen USP was transfilled on at least [redacted] days during this time period.

You have failed to ensure that each person engaged in the manufacture, processing and transfilling of this drug product, and each person responsible for supervising these activities, has the education, training, and experience to enable that person to perform their assigned functions in such a manner as to provide assurance that your drug product has the quality and purity that it purports or is represented to possess. In fact no one at your firm had received training commensurate with their responsibilities.

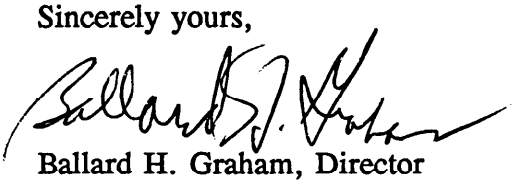
This lack of training was exemplified by the complete lack of understanding associated with the basic purity requirements for Oxygen USP by your transfiller and the individual responsible for reviewing his work. They expressed an unfamiliarity with all of the appropriate quality control steps required for transfilling. For example, an inspection by our investigator of a rack of cylinders available for distribution revealed four cylinders without labeling. These cylinders represented three separate filling dates (7/18/97, 8/14/97, and 9/9/97). There was no documentation of training for any of the individuals involved in the transfilling of Oxygen USP at your facility.

At the conclusion of the inspection, Investigator Andrews issued her Inspectional Observations (FDA 483) to and discussed her findings with you. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all inclusive list of violations that may be in existence at your firm. It is your responsibility to ensure that all requirements of the Act are being met at your facility.

You should take immediate action to correct these violations. Failure to promptly correct these deviations may result in legal sanctions provided by the law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of all warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You are requested to notify this office within fifteen (15) days of receipt of this letter of all steps you have taken, or intend to take, to correct these violations. We are aware that you voluntarily recalled the cylinders in distribution with low assay results. Your response should be addressed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District